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510(k) SUMMARY
AUTOCLAVABLE CAMERA HEAD OTV-Y0017

September 30, 2010

OCT 8 2010

1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5405
  FAX: 484-896-7128
  Email: stacy.kluesner@olympus.com

- Manufacturer: SHIRAKAWA OLYMPUS CO., LTD.
  3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
  Nishishirakawa-gun, Fukushima, Japan 961-8061
  Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: AUTOCLAVABLE CAMERA HEAD OTV-Y0017

- Common Name: CAMERA HEAD

- Regulatory Information:

Product Code	Device	Regulatory Description	Review Panel	Regulation Number	Device Class
FET	Endoscopic video imaging system/ component, gastroenterology -urology	Endoscope and accessories	Gastroenterology/ Urology	876.1500	II
NWB	Endoscope, accessories, narrow band spectrum	Endoscope and accessories.	Gastroenterology/ Urology	876.1500	II

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3 Predicate Device Information

- Device Name: HD CAMERA HEAD OTV-S7ProH-HD-L08E
- Common Name: CAMERA HEAD
- Manufacturer: SHIRAKAWA OLYMPUS CO., LTD.
  3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
  Nishishirakawa-gun, Fukushima, Japan 961-8061
  Establishment Registration No: 3002808148
- 510(k) No. K083155

4 Device Description

AUTOCLAVABLE CAMERA HEAD OTV-Y0017 is an imaging device used with specified Olympus video system center, light source, endoscope, and other ancillary equipment for observation of endoscopic image on a video monitor.

The new camera head is basically identical to predicate device in intended use, and similar in specifications, performance.

5 Indications for Use

This camera head has been designed to be used with the CV-180 EXERA II video system center or OTV-S7Pro VISERA Pro video system center, endoscopes, light sources, video monitors and other ancillary equipment for endoscopic diagnosis and treatment.

6 Comparison of Technological Characteristics

OTV-Y0017 is basically identical to the predicate device except for a change to the intended use (expanding beyond the bladder, urethra and kidney), specifications and method of sterilization. Comparison between the subject and predicate devices is shown in Table 3.

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Table 3. Comparison of Specifications
Subject Device: AUTOCLAVABLE CAMERA HEAD OTV-Y0017
Predicate Device: HD CAMERA HEAD OTV-S7ProH-HD-L08E (K083155)

Specifications		Subject Device OTV-Y0017	Predicate Device OTV-S7ProH-HD-L08E
Dimension	Camera Head	O.D. 38mm x 106mm (from mount surface) Straight-shape	O.D. 21mm x 83mm (from mount surface) L-shape
	Cable	O.D. 6.8mm x 4m	O.D. 3.3mm x 4m
Dimension	Weight	215g (excluding cable) 620g (total weight)	60g (excluding cable) 305g (total weight)
	Video plug	Card-edge type connector	Card-edge type connector
	Remote control switches	Embedded	Embedded
Observation	Pickup System	Interline type CCD solid-state image pickup	Interline type CCD solid-state image pickup
	Auto Iris	Not available	Not available
	Narrow Band Imaging (NBI) function	Available	Available
Operating Environment	Ambient Temperature	10 to 40°C	10 to 40°C
	Relative Humidity	30 to 85 %	30 to 85 %
	Atmospheric Pressure	700 to 1060 hPa	700 to 1060 hPa
Specifications		**Subject Device** OTV-Y0017	**Predicate Device** OTV-S7ProH-HD-L08E
Reprocessing	Cleaning	Immersible in detergent solution without water-resistant cap	Immersible in detergent solution without water-resistant cap
	Disinfection	Immersible in disinfectant solution without water-resistant cap	Immersible in disinfectant solution without water-resistant cap
	Sterilization	Autoclave sterilization	Ethylene oxide gas sterilization
Patient contacting material	-	No patient contacting material	No patient contacting material

7 Conclusion

When compared to the predicate device, OTV-Y0017 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

OCT 8 2010

Re: K102059
Trade/Device Name: AUTOCLAVABLE CAMERA HEAD OTV-Y0017
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: July 17, 2010
Received: July 28, 2010

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102059

Device Name: AUTOCLAVABLE CAMERA HEAD OTV-Y0017

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102059